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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE FIBROGEN, INC., SECURITIES LITIGATION

Case No. 3:21-cv-02623-EMC

CLASS ACTION

MOTION TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

Hearing Date: April 28, 2022
Time: 1:30 pm
Courtroom: 5
Judge: Hon. Edward M. Chen

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NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on April 28, 2022 at 1:30 p.m., or as soon thereafter as this motion may be heard in Courtroom 5, of the above-entitled court, located at 450 Golden Gate Avenue, San Francisco, CA 94102, FibroGen, Inc. ("FibroGen"), Enrique Conterno, James Schoeneck, Mark Eisner, and Pat Cotroneo will and hereby do move to dismiss with prejudice the Consolidated Class Action Complaint filed by plaintiffs Employees' Retirement System of the City of Baltimore, City of Philadelphia Board of Pensions and Retirement, and Plymouth County Retirement Association ("Plaintiffs") on October 29, 2021, and corrected on November 19, 2021 (the "CAC) (Dkt. 97). This Motion is made under Federal Rules of Civil Procedure 9(b) and 12(b)(6), and the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). This motion is based on this Notice of Motion; the accompanying Memorandum of Points and Authorities; Declaration of Alexander Kasner ("Kasner Decl."); the pleadings and papers on file in this matter; and such other matters as may be presented to the Court at the hearing.

STATEMENT OF RELIEF SOUGHT

Defendants seek an order under Rule 12(b)(6) dismissing with prejudice the CAC and each of its causes of action for failure to state a claim on which relief can be granted.

STATEMENT OF ISSUES TO BE DECIDED

A. Whether Plaintiffs have adequately alleged a claim under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act").

B. Whether Plaintiffs have adequately alleged a "controlling person" claim under Section 20(a) of the Exchange Act.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs' Consolidated Class Action Complaint ("CAC") alleges that FibroGen, Inc. (the "Company") and the five named individual defendants committed securities fraud over a nearly three-year period, from December 20, 2018 to July 15, 2021, in their public disclosures regarding roxadustat, a drug the Company is developing to treat anemia in patients with chronic kidney disease ("CKD"). Plaintiffs challenge 96 separate statements, from disclosures about the Company's interactions with the Food and Drug Administration to disclosures regarding pooled safety data from several Phase III trials. However, the CAC fails to adequately allege, under the strict pleading standards of the Private Securities Litigation Reform Act ("PSLRA"), falsity or scienter with regard to any of those statements. Accordingly, the CAC should be dismissed.

With regard to falsity, many of Plaintiffs' allegations are premised on a contorted reading of the statements Defendants actually made and are easily belied by viewing those statements in context. For example, Plaintiffs challenge a series of statements regarding the threshold – known as the non-inferiority margin – the FDA might apply to evaluate whether roxadustat is comparable, from a cardiovascular safety perspective, to current treatments. Yet, when read in context, the Company's statements were clear: while the threshold it was using had previously been used by the FDA in other related contexts, it had not reached any agreement with the FDA regarding the appropriate non-inferiority margin to be used when evaluating roxadustat's pooled safety data. Many of the other challenged statements are either inactionable opinion or corporate optimism or forward-looking statements protected by the PSLRA's safe harbor.

Plaintiffs' core theory of fraud arises from FibroGen's press release in April 2021 adding to certain earlier disclosures relating to the Company's assessment and analysis of cardiovascular safety data pooled from a number of Phase III trials. The CAC's assertion that the earlier disclosures were based on "manipulated" data to achieve a desirable result is not supported by a single well-pled factual allegation. In fact, the Company repeatedly informed investors it intended to apply multiple analyses and analytical methods to the cardiovascular safety data it presented to the FDA as part of its New Drug Application ("NDA") for roxadustat. And it is

undisputed that the Company's NDA submitted in late 2019 contained both the analyses reflected in the April 2021 release as well as the analyses contained in the Company's earlier disclosures (among many others). It is also undisputed that both sets of analyses support the same key conclusion: that, based on the pooled safety data, roxadustat's MACE risk was comparable to existing treatments for CKD anemia patients on dialysis, as well as those not yet on dialysis. Indeed, the FDA agreed and stated so publicly. Finally, as interpretations of clinical trial data are opinions, Plaintiffs must allege, with particularity, that Defendants' beliefs were objectively and subjectively untrue. No such facts are alleged here.

The CAC should be dismissed for a second, independent reason: it fails to plead facts that give rise to a cogent and compelling inference that any defendant intended to deceive investors. The CAC fails to reference a single email or contemporaneous document providing any insight into the state of mind of any defendant. While Plaintiffs cite three confidential witnesses ("CWs") (each a former employee of AstraZeneca, FibroGen's partner in the development of roxadustat), not one is alleged to have had a single conversation with any of the defendants, and the vague statements attributed to the three CWs by Plaintiffs simply are not indicative of scienter. Moreover, the theory of this case simply is not plausible. It would require this Court to infer that six individuals conspired with each other (even though two of them had no relationship whatsoever with the Company at the time of the earlier disclosures, and two others were no longer employed by the Company at the time of the April 2021 disclosures), as well as with FibroGen's development partner AstraZeneca (who disclosed the *same* purportedly misleading results as FibroGen), to present the safety data in a misleading way; that the presentation of the data as well as the underlying data itself was shared in its entirety with the FDA, who they knew would closely scrutinize it; and that they did so knowing roxadustat would never be approved and the Company would "face the inevitable fallout." *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020). This simply "does not make a whole lot of sense." *Id.*

The only cogent inference to be drawn from the allegations as well as the materials subject to judicial notice is that Defendants acted in good faith throughout the Class Period. The fact that FibroGen expressed some level of confidence regarding roxadustat's safety profile and the

potential for approval by the FDA should come as no surprise given that roxadustat has been approved for sale to treat CKD anemia in eight of the ten largest pharmaceutical markets. Further, the fact that the Company decided to issue the April 2021 release to provide additional information is inconsistent with the nefarious conclusion Plaintiffs require this Court to make.

Accordingly, Defendants respectfully request that the CAC be dismissed with prejudice.

II. RELEVANT FACTS AND ALLEGATIONS

A. FibroGen and Roxadustat

FibroGen, based in San Francisco, develops medicines for the treatment of anemia, fibrotic disease, and cancer. (¶ 39.)[1] FibroGen's most advanced product is roxadustat, an oral treatment for anemia – a condition marked by low levels of hemoglobin ("Hb") in red blood cells – in patients with CKD. (*Id.*; Ex. E at 4.) Although not yet approved in the United States, roxadustat is approved for the treatment of CKD anemia in Europe, China, Japan, Chile, and South Korea. (Ex. ZZ at 2.) In the United States, FibroGen partnered with AstraZeneca PLC ("AstraZeneca"), a global pharmaceutical company, to develop and commercialize the drug. (*Id.*; ¶ 38.) In that role, AstraZeneca has full access to all roxadustat data and shares responsibility for preparing and submitting regulatory applications in the U.S. (¶ 38; Ex. L at 21, 26; Ex. N at 11.)

The current standard of care for patients suffering from CKD anemia are erythropoiesis-stimulating agents ("ESAs"), which stimulate red blood cell production. (¶ 39.) ESAs have two primary drawbacks: they (1) are administered by injection and, therefore, require the patient to visit a doctor to receive treatment, and (2) are known to increase the risk of Major Adverse Cardiac Events ("MACE") and other serious side effects. (¶ 40.) Roxadustat, administered orally, eliminates the need for a doctor's visit and, because it is not an ESA, has the potential to be an effective treatment for less severe CKD patients, including those not on dialysis. (¶ 41.)

B. Roxadustat Phase III Studies – Efficacy Results

FibroGen, in collaboration with AstraZeneca and another partner, conducted one of the

[1] "Ex." refers to exhibits to the Declaration of Alexander Kasner ("Kasner Decl.") filed herewith. "¶" refers to the CAC. (Dkt. 97.) "#" refers to statement numbers in the Appendix attached to the Motion. Unless noted, all emphasis is added and internal quotation marks, ellipses, brackets, and citations are omitted.

largest and most complex Phase III clinical programs in history consisting of a total of eight trials of roxadustat, six of which would directly support a potential NDA in the U.S. (¶ 46; Ex. VV at 14.) The studies were designed to determine whether roxadustat was effective and safe in treating CKD anemia in two populations: those not on dialysis ("non-dialysis-dependent" or "NDD") and those on dialysis ("dialysis-dependent" or "DD"), including a sub-population known as incident-dialysis ("ID").[2] (Ex. I; ¶ 46.) The NDD studies were double-blind, randomized, and compared roxadustat to placebo, whereas the DD studies were randomized but open-label, and compared the drug to ESAs. (¶ 46.) The primary efficacy endpoint (i.e., the main result that would be measured to see if roxadustat worked) was the increase in a patient's hemoglobin levels. (Ex. E at 1.) For each Phase III trial, FibroGen submitted Statistical Analysis Plans ("SAPs") to the FDA explaining the statistical methodology it would use to measure efficacy, including the stratification factors[3] that would be used in that study. (*See, e.g.*, Ex. C at 10, 12.)

On December 20, 2018, the first day of the Class Period, FibroGen issued a press release disclosing "topline" efficacy results from three Phase III trials. (¶ 50.) The results were positive, as roxadustat met the primary efficacy endpoint of change in Hb levels in each patient population. (Ex. E; Ex. F.) The release contained a quote from defendant Dr. Peony Yu ("Yu"), the Company's Chief Medical Officer: "We are excited to have achieved superiority in efficacy not only against placebo but also over active comparator in our studies." (Ex. E at 4.) This is the first of the 96 statements challenged by Plaintiffs, yet the CAC contains no well-pled allegations that the detailed efficacy data or Yu's characterization of that data was false or inaccurate.

C. Roxadustat Phase III Studies – Safety Results

Design of the Pooled Safety Analysis. Because of serious cardiovascular ("CV") risks associated with ESAs, the FDA asked FibroGen to determine roxadustat's potential impact on CV risk. (Ex. XX at 31-32.) Because none of the individual studies were large enough to adequately measure CV risk, FibroGen and AstraZeneca, consulting with the FDA, planned to pool the safety

[2] Incident Dialysis ("ID") patients are those who started dialysis within four months of the study. (Ex. E at 2, 3.)

[3] "Stratification factors" refer to grouping clinical trial subjects to ensure balance in treatment arms by factors such as by race, sex, geographic location, and other demographic categories

data from six individual Phase III trials. (Ex. WW at 44-45, 82.) Although agreement was not reached until the pre-NDA meeting in July 2019, the FDA advised FibroGen that the primary endpoint used to assess CV risk would be the time to first MACE[4]; that is, the time period in which patients on roxadustat first suffered a MACE compared to patients on ESAs (in DD studies) or on placebo (in NDD studies). (Ex. WW at 82; Ex. VV at 7-8; ¶ 48.)

FibroGen ultimately submitted two Pooled Statistical Analysis Plans ("PSAPs") to the FDA, one for the pooled NDD and one for the pooled DD safety studies. (*See, e.g.*, Ex. C at 12; Ex. B at 99.) The PSAPs provided a framework to combine the safety data from the individual Phase III studies, which were similar but not identical as they had, *e.g.*, some different enrollment criteria and stratification factors in their individual SAPs. (*Id.*) For example, since the studies took place in different countries, some of the SAPs for the individual studies required analyses to stratify patients based on whether they lived in or outside the United States (*e.g.*, Ex. D at 9), while others stratified whether patients lived in or outside of Europe (*e.g.*, Ex. B at 73). Importantly, the PSAPs provided that FibroGen would analyze the safety data several different ways, using both the various stratification factors set forth in the individual study plans as well as other "common" stratification factors typically used to assess clinical trial data. (*See, e.g.*, Ex. B at 137.) Moreover, as the Company made clear to investors during the Class Period, the FDA, in assessing roxadustat's overall safety profile, would ultimately look at the "totality of evidence." (*See, e.g.*, Ex. I at 2; Ex. R at 12.)

Results of the Pooled Safety Analysis. While the December 20, 2018, press release discussed above focused on efficacy, it also stated that "the preliminary safety analyses of each of these three individual studies show an overall safety profile consistent with the results observed in prior Roxadustat studies." (¶ 143; #4.) Plaintiffs allege that statement was false, yet the CAC does not explain how the statement was false or how the safety results from these three studies differed from any earlier studies.

On May 9, 2019, FibroGen disclosed the topline results of the **pooled** safety analyses, combining the safety data from the three NDD and three DD studies. The Company disclosed

[4] MACE is defined as all-cause mortality, myocardial infarction, and stroke. (Ex. L at 22.)

that, based on the pooled analyses, there was no clinically meaningful difference in MACE risk in DD patients on roxadustat and those on ESA, and in NDD patients on roxadustat and those on placebo. (Ex. I at 2-3.) The Company also disclosed that for the ID sub-group, the data indicated a "trend toward reduced risk" of MACE. (*Id.*) In its Form 10-Q filed that same day, the Company warned: "While we will present to regulatory authorities certain pre-specified and not pre-specified sub-populations and sub-group analyses (for example, incident dialysis), multiple secondary endpoints, and multiple analytical methods (such as long-term follow up analyses), including adjusted and censored data, regulatory authorities may reject these analyses, methods, or even parts of our trial design or certain data from our studies, the rationale for our pre-specified non-inferiority margins or other portions of our statistical analysis plans." (Ex. L at 46.)

Later that same day during the Company's quarterly earnings call, analysts asked about the pooled safety data. (Ex. J at 12-23.) For example, they asked whether the pooled data indicated that roxadustat was "non-inferior" from a MACE-risk perspective to ESA in the DD population and to placebo in the NDD population. "Non-inferiority" is a statistical concept used by the FDA to measure whether a study drug likely presents similar risk of the event studied (in this case to the primary endpoint of time to first MACE) than the risk of such events in the control groups. A hazard ratio, calculated using complex regression models, is the model's best estimate of the relative risk between a study drug and its comparator. (http://www.bandolier.org.uk/painres/download/whatis/What_are_haz_ ratios.pdf). Researchers typically then calculate the lower and upper bound of the hazard ratio's "95% confidence interval" (*i.e.,* a range of values intended to capture with a 95% confidence level the range within which the actual hazard ratio falls). For instance, a study comparing the relative safety risk of a new drug to standard of care might generate a hazard ratio of 1.1, with a 95% confidence interval of .7 to 1.25, indicating a best estimate that the study drug is 10% less safe than the comparator, with a 95% confidence level that the study drug is between 30% safer and 25% less safe than the comparator. Whether such data supports a regulatory conclusion that the study drug is non-inferior depends on the FDA's determination as to the acceptable range of statistical risk, defined by the upper bound of the 95% confidence interval. Thus, in this example, even though the best

estimate of risk might be that the new drug is less safe, should the FDA apply a "non-inferiority margin" of 1.3 to the upper bound of the 95% confidence interval, the data would support a conclusion that the study drug was non-inferior to the comparator, as the upper bound (1.25) is below the 1.3 non-inferiority margin. In contrast, were the FDA to apply a non-inferiority margin of 1.2 to the study, one could not conclude that the drug was statistically non-inferior.

In responding to these questions during the call, the Company's CEO, Thomas Neff, and Yu made clear: (1) the upper bound of the confidence interval to first MACE for the DD and NDD populations was below a 1.3 non-inferiority margin (Ex. J at 17); (2) a 1.3 non-inferiority margin is a "standard" or "conventionally accepted" non-inferiority margin based on the FDA's diabetes guidance (*Id*. at 17, 20); and (3) the Company had not reached an agreement with the FDA as to what non-inferiority margin the FDA would apply in its evaluation of the safety data (*Id*. at 20-21).[5] Thus, Yu explained that the Company was using a 1.3 standard for non-inferiority, which had "previously been used by U.S. regulator[s] for assessment of cardiovascular safety in similar types" of studies and that, "[i]f we use that standard, the answer is yes, we have achieved non-inferiority." (*Id*. at 20-21.) Neff added: "In the U.S., there are multiple noninferiority margins that are under discussion," and "we have to yet agree with our regulator on specific analyses to be done."[6] (*Id*. at 12.) Neff also explained that it was "hard[] to sum this up in 1 sentence or 2 sentences" due to uncertainty around the standards of review the FDA would apply and the expectation that the data would be reviewed on a "totality of evidence basis." (*Id.* at 15.) Based on this data and the efficacy data, Yu stated that the Company "was excited about the potential of roxadustat as an innovative new therapy for CKD patients." (*Id*. at 9.)

Consistent with its prior warning in the 10-Q that it would analyze the data using "certain pre-specified and not pre-specified sub-populations and sub-group analyses" (Ex. L at 46)

[5] This last point was, as the Company made clear, in contrast to the regulatory situation in Europe, where the Company had reached an agreement on the non-inferiority margin for its marketing approval submissions to the European Medicines Agency ("EMA"). (*Id*.)

[6] *See also id*. at 12 ("there is a discussion planned with the FDA about these various analyses . . . we have to yet agree with our regulator on specific analyses to be done . . . [t]here are back and forth discussions"); Ex. U (explaining FDA guidance for inferiority margins is "strictly for diabetes medicines," "[t]here is no such guidance for CKD amenia…this will become a product review issue when [the FDA] look[s]at the benefit/risk profile of the product."); Ex. OO at 10 ("there was no agreed-upon upper bound . . . 1.3 was not agreed upon . . . with the FDA.").

FibroGen explained that it was continuing to analyze the data "stratified by" different categories. (Ex. J at 6.) Neff noted that "there is agreement from [the FDA] that we can make statistical adjustments." (*Id.* at 17); (*see also* Ex. M at 7) (explaining Company would continue to look at the data from "different angle[s]" using "different cut[s]").

On November 8, 2019, FibroGen, AstraZeneca, and Dr. Robert Provenzano, a Professor at Wayne State University and primary investigator in the global Phase III program, presented detailed results from, among other things, the pooled CV safety analyses at a conference of the American Society of Nephrology ("ASN"). (Ex. P; ¶ 61.) FibroGen and AstraZeneca also disclosed the more detailed results in press releases that same day. (*Id.*; Ex. Q.)

D. The Roxadustat NDA

NDA Submission. In July 2019, the FDA held a pre-NDA meeting with FibroGen and AstraZeneca to discuss the content of the anticipated NDA.[7] (¶¶ 59, 167.) In that meeting, FibroGen and the FDA reached agreement on the primary safety endpoint upon which the FDA would base its review (time to first MACE). (Ex. S at 28.) Further, with regard to the NDD trials – during which patients on placebo dropped out at very high rates, potentially skewing the results – the Company and the FDA agreed to an "Intent-to-Treat" ("ITT") methodology, which would measure time to MACE for each study patient through the end of the study, regardless of whether they were still receiving study treatment. (Ex. J at 5-6; *see also* Ex. XX at 69-70; Ex. VV at 13.)

In August 2019, Neff unexpectedly passed away. (¶ 5, n.1.) He was replaced as CEO on an interim basis by defendant James Schoeneck, a member of the Company's board of directors. (¶ 21.) The board appointed defendant Enrique Conterno, who had not previously been with the Company, as the permanent CEO on January 6, 2020. (¶ 19.)

On December 23, 2019, FibroGen, with AstraZeneca's review and approval, submitted the roxadustat NDA to the FDA. (¶ 66.) In the NDA, FibroGen presented multiple sets of analyses of the pooled CV safety data, including some labeled as "primary" and others designated as "sensitivity" analyses. (Ex. YY at 86.) The primary analyses used both the stratification factors

[7] In a Pre-NDA Meeting, a drug sponsor and the FDA address specific questions related to the NDA filing to ensure the submission is well-organized and complete. (FDA Guidance, *IND Meetings for Human Drugs and Biologics*, at 8, https://www.fda.gov/media/70827/download.)

identified in the individual SAPs and other "common" stratification factors, which the PSAPs contemplated would be used. (*Id.*; *see supra* at 5.) The sensitivity analyses utilized only the stratification factors identified in the individual SAPs. (*Id.*) The FDA accepted the NDA in February 2020 and set a PDUFA date[8] of December 20, 2020. (¶ 66; Ex. V at 5.)

Although Defendants publicly expressed their confidence in roxadustat's overall risk profile as reflected in the NDA (s*ee, e.g.*, ¶¶ 67-68), they also repeatedly warned investors that approval was uncertain and that, if roxadustat was approved, the FDA-approved label might contain a "black box" warning similar to that required for ESAs. (Ex. L at 41, 47.) Indeed, Conterno stated that he assumed the FDA would require a "black box" warning (Ex. V at 9; *see also* Ex. BB at 7; Ex. EE at 6 (it's "difficult to handicap what we'll end up with the FDA"); Ex. HH at 3; and Ex. II at 5-6.) The Company included similar cautionary language in its filings with the SEC. (*See, e.g.*, Ex. L at 47; Ex. W at 56.) Conterno and Yu also continued to warn investors that the FDA might convene an Advisory Committee ("AdCom") of outside experts to provide insight and recommendations to the FDA prior to its NDA decision. (Ex. U at 10; Ex. Y at 7; Ex. BB at 8.) At the mid-cycle meeting in June 2020, the FDA indicated that an AdCom was not planned. (Ex. CC at 5, 9; ¶ 207.)[9]

Two days before the PDUFA date, on December 18, 2020, the FDA announced that it was extending its review of the NDA and set a new PDUFA date of March 20, 2021. (¶ 73.) Three months later, on March 1, 2021, the FDA announced that it would hold an AdCom. (¶ 74.)

April 6, 2021 Press Release. On April 6, 2021, FibroGen issued a press release containing additional details regarding the pooled CV safety analyses contained in the NDA and publicly disclosed by the Company. (Ex. PP at 1.) The release included a table containing the hazard ratios and confidence intervals for the different study populations based both on the stratification factors used in the analysis underlying the Company's May and November 2019

[8] This is the deadline under the Prescription Drug User Fee Act, for the FDA to make a decision on an NDA. (¶ 66.)

[9] On December 1, 2020, FibroGen announced that Yu, who had led the global Roxadustat program, would retire on December 20, 2020, the anticipated PDUFA date, and would continue as a consultant. The Company appointed Dr. Mark Eisner ("Eisner") as the new CMO as of December 21, 2020. (Ex. JJ; ¶ 72.)

disclosures and the stratification factors in the underlying SAPs for each of the separate studies (the "pre-specified" stratification factors). (*Id.*) In every single one of these analyses, the upper bound of the 95% confidence interval was below 1.3. (*Id.*) The release made clear that the additional information did not relate in any way to roxadustat's efficacy, nor had there been any change in the underlying safety data. (*Id.; see also* Ex. QQ at 4.) Furthermore, the release made clear that all the data in the release had been included in the NDA filing the year before. (Ex. PP at 1.) Importantly, as reflected in the release, the additional analyses did not impact the Company's conclusions regarding "the comparability, with respect to cardiovascular safety, of roxadustat to epoetin-alfa [ESA] in dialysis-dependent (DD) patients and to placebo in non-dialysis dependent (NDD) patients." (*Id.*) However, based on the additional analyses, the Company could not conclude that roxadustat reduced the risk of (or was "superior" to) ESA for ID patients because even though the estimated 0.82 hazard ratio was still below 1 (indicating a trend toward reduced risk), the upper bound of the confidence interval was above 1.[10] (¶ 81.)

FDA Advisory Committee. The FDA held its AdCom meeting to consider roxadustat on July 15, 2021, the last day of the Class Period. (¶ 104.) The FDA concluded that roxadustat presented "no significant difference in the risk of MACE" for the NDD and DD populations and "[t]he findings were qualitatively similar, regardless of the stratification factors." (Ex. XX at 169-71; Ex. VV at 47.) The FDA also made clear that roxadustat's "efficacy is not in question." (Ex. VV at 7.) Yet, the members of the AdCom voted to recommend that the FDA not approve the drug. (¶ 112.) They seemed particularly concerned that the high dropout rate of patients in the placebo arm of the NDD studies created a "challenging" data set that was "difficult to interpret" and potentially biased the results. (Ex. XX at 25, 157, 162, 165.) Some members of the AdCom also expressed concern about the risk of thrombosis and other safety issues unrelated to MACE.[11] (¶¶ 112, 118; *see* Ex. XX at 29-32, 49-52). The AdCom's recommendation was not

[10] The pooled safety analyses using the pre-specified stratification factors resulted in slightly different results looking at MACE+, rather than MACE, as the endpoint. (Ex. PP at 1-2.) As discussed above, FibroGen and the FDA had agreed to use MACE as the primary endpoint for the NDA. (Ex. S at 28.) MACE+ was an endpoint that the EMA looked at. (Ex. J at 5.) The EMA approved Roxadustat on August 19, 2021. (Ex. ZZ.)

[11] The Company had already disclosed that roxadustat's "most frequently reported adverse events were diarrhea, hypertension, pneumonia, headache and arteriovenous fistula **thrombosis.**" (Ex. S

based on the decision of which stratification factors were used in the analyses.

On August 11, 2021, FibroGen announced that it received a Complete Response Letter from the FDA declining to approve roxadustat and requesting additional clinical studies. (¶ 119.)

The following week, on August 19, 2021, the European Commission approved roxadustat to treat anemia associated with CKD in both NDD and DD patients, with data from the same Phase III studies included in the NDA. (Ex. W at 5-6; Ex. ZZ.) The drug had already received regulatory approval in China, Japan, Chile, and South Korea. (Ex. YY at 2.)

E. Plaintiff's Complaint

The operative CAC was filed on November 19, 2021 (Dkt. 97). The CAC alleges that Defendants violated Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, challenging 96 statements that the Company made from December 20, 2018 through July 15, 2021 about (1) whether roxadustat would, if approved, receive a "black box" warning label, (2) the non-inferiority margin that FibroGen used in its safety analyses, (3) roxadustat's efficacy, (4) the results of the pooled safety analyses, and (5) expressions of optimism about roxadustat's potential and the likelihood of FDA approval. The CAC names FibroGen, Yu, Schoeneck, Conterno, Dr. Mark Eisner, the Company's new CMO, and Pat Cotroneo, who was FibroGen's CFO during the Class Period.

III. LEGAL STANDARDS

To plead a claim under § 10(b) and Rule 10b-5, Plaintiffs "must allege: (1) a material misrepresentation or omission by the defendant (falsity); (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance []; (5) economic loss; and (6) loss causation." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1057 (9th Cir. 2014). Under the PSLRA and Rule 9(b), every element of a securities fraud claim must be pled with particularity. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009); *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598 (9th Cir.

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at 32. *See also, e.g.*, Ex. DD at 52 (noting that roxadustat had the following warning in Japan: "Serious **thromboembolism** such as cerebral infarction, myocardial infarction, and pulmonary embolism may occur, possibly resulting in death, during treatment with Roxadustat" and that a similar warning could be required in the U.S.).)

2014). Plaintiffs must allege the "who, what, when, where, and how" of the alleged fraud, and "set forth what is false or misleading about a statement, and why it is false." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

IV. ARGUMENT

A. Plaintiffs Fail to Adequately Plead Falsity

While Plaintiffs present a sensationalized (and untrue) account of data "manipulation," "utterly false" statements, and "lie[s]" (¶ 3), they fail to plead falsity as to any statement.

1. Statements Regarding Potential Black Box Warning

Plaintiffs assert that Defendants Conterno and Yu (and non-defendant Neff) misled the market, between May 2019 and September 2020, that the FDA would not require a "black box" warning on the Roxadustat label if approved. (*See* ##21, 24, 42, 51, 54-56, 60, 67-68.) But Plaintiffs ignore Defendants' statements that not only was a black box warning possible, it was assumed. In May 2019, Yu first told investors that "what the FDA puts on the label is something . . . we may not have much control over. (#21.) Similarly, Conterno told the market that he *assumed*, if approved, roxadustat would carry a black box warning: "the ***base case*** for me is . . . that we get a black box." (Ex. U at 9.) He reiterated this point in September 2020, noting that it was "difficult to handicap what we'll end up with the FDA." (Ex. EE at 6.) Further, the CAC fails to allege that the FDA ever indicated that it would require a black box for roxadustat. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (statements not misleading where they create no "impression of a state of affairs that differs in a material way from the one that actually exists").

2. Statements Regarding Applicable Non-Inferiority Margin

Plaintiffs next assert that Defendants Yu and Conterno (and non-defendant Neff) falsely implied to investors that the FDA had agreed to a non-inferiority margin of 1.3 for the pooled safety analyses because they referred to a "standard," "reference," or "commonly applied" 1.3 non-inferiority margin in sharing their analyses. (*E.g.*, ##9, 17, 19-21, 24, 32, 34-35, 38, 43, 49, 59, 84.) Again, Plaintiffs ignore that FibroGen stated time and again that it *had not* reached agreement with the FDA. For example, in May 2019, Neff was clear that, "there are multiple

noninferiority margins that are under discussion." (Ex. J at 12.) Because the FDA did not provide non-inferiority margin guidance for CKD anemia, (Ex. U at 8), the Company disclosed that it analyzed the data based on a "reference" or "commonly applied" non-inferiority margin of 1.3 that the FDA had accepted for other drugs, such as diabetes medicines (Ex. I at 3, Ex. P at 3-4, Ex. OO at 10). The market understood this, with analysts noting "*there is no statistical agreement on upper and lower bounds*." (Ex. K at 1.) Plaintiffs' attempt to misconstrue Defendants' words to mean that the FDA endorsed a 1.3 non-inferiority margin is "neither plausible nor reasonable." *Weller v. Scout Analytics, Inc.*, 230 F. Supp. 3d 1085, 1093 (N.D. Cal. 2017) (rejecting characterization of statements because "no reasonable investor could read [them] in the way Plaintiff suggests").

Ignoring Defendants' actual disclosures, Plaintiffs rely on a comment by one FDA reviewer in July 2021 at the AdCom – long after the challenged statements – that the FDA "had a goal of 1.25," which was allegedly discussed during "meetings" with unnamed FibroGen employees. (¶ 55.) But Plaintiffs do *not* allege that the FDA actually applied a non-inferiority margin of 1.25 in its review. Indeed, the FDA's conclusion of "no significant difference in the risk of MACE" (Ex. XX at 169-71) between roxadustat and placebo even with a 95% upper bound confidence interval of 1.27 supports just the opposite conclusion. Nor do they allege that the FDA informed Defendants that it would apply a 1.25 non-inferiority margin, when such "meetings" occurred, or with whom. In fact, the FDA confirmed that there was no agreement (Ex. VV at 47) and never mentioned 1.25 in its AdCom materials. During the AdCom, Dr. Ellis Unger, head of the FDA office responsible for reviewing the roxadustat NDA, noted that the non-inferiority margin was "arbitrary" and "1.3 is reasonable." (Ex. XX at 195.) Given Defendants' transparency that they were applying a "reference" 1.3 non-inferiority margin *without agreement from the FDA*, there was nothing misleading about the statements.

3. Statements Regarding Roxadustat's Efficacy

Plaintiffs also challenge numerous statements about roxadustat's *efficacy*, such as "[w]e are excited to have achieved superiority in efficacy" (##1, 6-7, 24) and that the studies showed "improved" or "positive" efficacy, referring to data showing increased hemoglobin levels (##2,

11, 12), as well as statements regarding efficacy benefits, such as that "patients had a 33% reduction in the risk of blood transfusion compared to epoetin [alfa]" (##3, 13, 16, 23, 50, 62, 66; *see also* 5, 28, 47, 56, 63, 72, 93). But Plaintiffs do not allege that any efficacy data referenced in the statements were misstated in any way, or that any of the challenged statements were otherwise false or misleading.[12] Perhaps given this fundamental flaw, Plaintiffs argue that there was "no proof of any efficacy" because of "far too many serious safety signals." (¶ 144.) This conflates efficacy with the FDA's risk benefit analysis, which assesses whether the benefits (efficacy) of a product warrant its risk (safety). As the FDA confirmed in July 2021, "roxadustat's efficacy is not in question" as "[a]ll studies . . . demonstrated efficacy." (Ex. VV at 7.)

4. Statements Regarding The Pooled CV Safety Analyses

Plaintiffs challenge 78 statements about the results of roxadustat's pooled safety analyses (*see* Appendix), claiming that Defendants failed to inform the market that the Company made "post hoc" changes to the stratification factors used to assess the safety data. (*E.g.* ¶ 182.) These fall into three categories: (1) statements about MACE risk comparability or non-inferiority to epoetin alfa or placebo (2) statements about MACE risk superiority in the ID subpopulation, and (3) expressions of confidence or excitement about roxadustat's safety data.

As an initial matter, *all* statements interpreting the safety data – *i.e.*, that roxadustat was comparable from a MACE perspective to the comparators in both the DD and NDD populations, and was superior in the ID sub-population – were opinions. (##4, 7-11, 14-18, 20-24, 26-33, 37-54, 56, 58-72, 74, 76-77, 79-88, 90-96.) "[P]ublicly stated interpretations of the results of various clinical studies . . . are essentially no different than opinions." *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011). Because "[r]easonable persons may disagree over how to analyze data and interpret results,[] neither lends itself to objective conclusions." *Id.* at 567 n.20. Further, the Company generally framed its conclusions about the pooled safety data as beliefs: "***we believe*** there is no clinically meaningful difference in MACE risk" (## 8, 22); "***we believe*** our MACE results in dialysis and in non-dialysis also support the conclusion of no

[12] Nor do they plead that Defendants did not sincerely believe in the efficacy of roxadustat. Thus, such statements of opinion (##7, 63, 72) are not false or misleading. *See infra* at 14-16, 19.

increased cardiovascular safety risk" (#23); "***we continue to believe*** that in non-dialysis, we basically show comparability relative to placebo" (#84).

The CAC does not allege that any Individual Defendant who shared those conclusions did not sincerely believe they were reasonable interpretations of the data, thus Plaintiffs fail to plead they were false. *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 180, 186 (2015) (holding statements that "we believe we are obeying the law" and "we believe that our contracts … are legally and economically valid" could not be affirmatively false because the plaintiffs "do not contest that Omnicare's opinion was honestly held"). Nor do they plead that the opinions turned out to be wrong (at least as to NDD and DD) as the FDA *agreed* that the MACE risk "findings were qualitatively similar, regardless of the stratification factors." (Ex. VV at 47.) *See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615 (9th Cir. 2017) (to plead fraud, plaintiff must allege "speaker [did] not honestly hold the stated belief *and* the belief [was] objectively incorrect").

The CAC also fails to plead that the Company's interpretation of the safety data was misleading based on any alleged omission. To plead such theory, Plaintiffs must allege specific facts establishing that the Company did not have a reasonable basis for those conclusions. *See Omnicare*, 575 U.S. at 198. The CAC fails to do so. The Company was always transparent that its conclusions were based on: (1) a "reference" 1.3 non-inferiority margin (that investors knew had not been agreed to by the FDA); (2) an expectation that the FDA would consider the "totality of evidence"; and (3) certain "prespecified and not pre-specified" analyses. Further, the CAC does not allege that the Company's calculations were wrong. The fact that AstraZeneca published the same conclusions further bolsters the reasonableness of the Company's opinions.

Further, the court must analyze whether an opinion statement is "misleading to a reasonable person reading the statement fairly and in context," which "is no small task for an investor." *Omnicare*, 575 U.S. at 194. To do so, the Court must consider the Company's robust disclosures about the basis for its conclusions and the risk that the FDA might disagree with them. *Id*. at 196 ("the court must take account of whatever facts [defendant] did provide . . . as well as any other hedges, disclaimers, or qualifications it included" to determine whether opinion

statements are misleading in context). Here, no reasonable investor could be misled into believing that the Company's opinions about the safety data were the only possible interpretation, or that the FDA would necessarily agree with them. Indeed, the Company's risk factors were both robust and prescient. It warned that even though it believed the totality of the evidence using various statistical methods supported approval, the FDA "will do their own benefit risk analysis and may reach a different conclusion than we or our partners have internally, and these regulatory authorities may base their approval decision on different analyses, data, and statistical methods than ours." (Ex. W at 54.)[13]

Plaintiffs' theory as to many of these statements also fails from a temporal perspective. The first 24 statements were made between December 20, 2018, and June 12, 2019. (*See* Appendix.) To the extent Plaintiffs claim that statements regarding the safety results were misleading because they were not based on "prespecified analyses required by the FDA" (*see, e.g.*, ¶ 144), the arguments fail. First, the CAC fails to identify which prespecified analyses were allegedly not followed, and completely ignores that the Company disclosed that it would present multiple analyses of the pooled data and the analyses methods would be discussed with the FDA *after* unblinding. (Ex. L at 22, 46.) Second, it was not until the pre-NDA meeting with the FDA in July 2019, after the first 24 challenged statements were made, that the FDA and FibroGen reached agreement regarding the analysis methods. (*E.g.*, Ex. J at 6 ("[W]e have not yet spoken with the FDA. . . . [T]here is a discussion planned with the FDA about these various analyses.").) The statements could not have been false because they purportedly did not follow the "analyses required by the FDA" (¶ 144) as no such analyses existed until *after* the statements were made.

Plaintiffs' theory that the Company's statements regarding the results of the pooled safety study also fails when each category of statements is analyzed separately.

Comparability/Non-Inferiority in DD/NDD. Plaintiffs challenge nearly 40 statements

[13] The Company also warned: that FDA approval of roxadustat might be delayed or denied if the FDA required additional clinical trials to demonstrate efficacy and safety (exactly what the FDA did in August 2021); that the FDA "may change their approvability criteria"; and that the FDA and other regulatory authorities may "reject [its] analyses, methods or even parts of our trial design or certain data from our studies … or other portions of our statistical analysis plans." (Ex. W at 54). Similarly robust risk disclosures occurred throughout the Class Period.

repeating the opinion, first reported in May 2019, that "***we believe*** there is no clinically meaningful difference in risk of MACE between roxadustat" and Epogen, in the DD population, and placebo, in the NDD population based on the pooled safety data. (Ex. I; ## 8-13; *see also* ##16, 18, 22, 23, 24, 29, 31-33, 38, 40, 44-45, 47, 48, 51-52, 59, 61, 64, 66, 70-71, 79, 81-88, 90, 92-94, 96.) Plaintiffs' theory appears to be premised on the fact that, in the Company's April 2021 press release, it provided additional analyses of the same data that generated slightly different results. However, the additional analyses did not change those conclusions. Indeed, the Company reiterated in the April 2021 release the same conclusions regarding comparative MACE risk in the NDD and DD trials. (Ex. PP at 1.) The FDA apparently agreed, concluding there was "no significant difference in the risk of MACE" between the drug and its comparators. (Ex. XX at 169-71; *see also* Ex. VV at 47 ("[t]he findings were qualitatively similar, regardless of the stratification factors").)[14] Without particularity in its pleadings challenging either the accuracy of the numbers contained in the analyses or the conclusions drawn from them, Plaintiffs' challenges to these statements must fail. *In re Regulus Therapeutics Inc. Sec. Litig.*, 406 F. Supp. 3d 845, 857 (S.D. Cal. 2019) (dismissing claims where plaintiff offered only "vague and impressionistic . . . allegations regarding the contradictory . . . results purportedly held by Defendants").

Superiority in ID. Plaintiffs further challenge the Company's conclusion, first shared in a November 2019 press release, that roxadustat's safety data demonstrated "superiority" in MACE risk for the ID sub-group. (*See, e.g.*, ##17, 22, 23, 29, 32-33, 40, 44-46, 50-54, 66, 69, 74, 95.) It is true that the Company's April 2021 press release stated that, based on analyses using "pre-specified" stratification factors, it could not conclude that there was statistical "superiority" in MACE for the ID group (Ex. RR). However, this fact, acknowledged by the Company on April 6, 2021, does not render the Company's previously-shared conclusions false or misleading. As an initial matter, there was never any agreement with the FDA that FibroGen would submit data

[14] The results disclosed on April 6, 2021 as to MACE risk for NDD and DD differed slightly from those disclosed before, but they ultimately made no difference. For example, the hazard ratio was .96 with a confidence interval of .82 to 1.13 for DD in the analysis disclosed at ASN, while the hazard ratio was 1.02 with a confidence interval of .88 to 1.2 in the additional analysis disclosed April 2021. (Ex. P; Ex. PP.) Ultimately, both FibroGen and the FDA concluded there was no meaningful clinical difference between the drug and its comparators.

regarding the ID subgroup as part of the NDA nor how, if at all, the data from the ID group would be analyzed. The Company made this clear in its SEC filings throughout the Class Period: "[W]e will present to regulatory authorities ***certain pre-specified and not pre-specified sub-populations and sub-group analyses*** (***for example, incident dialysis***), multiple secondary endpoints, and multiple analytical methods." In fact, the Company repeatedly stated that it would undertake, and its NDA would present, numerous analyses based on different factors. (*See, e.g.*, Ex. I; Ex. J at 17-20; Ex. L at 46.) As a result, the fact that the Company was able to reach one conclusion based on one analysis that was not borne out upon further analyses was a risk inherent in the process disclosed to the public. Moreover, neither the May nor November 2019 disclosures indicated what statistical methodology or specific stratification factors were used.

And while the CAC makes much of the fact that the stratification factors used in the primary analyses were applied "post hoc," this is a red herring. Defendants were clear that the determination of the pooled safety analyses would be based upon agreement with the FDA *after* the Phase III trials were unblinded and the topline CV data was reported in May 2019. (Ex. J at 6, 12, 16) (stating that FibroGen had no agreement with the FDA on the primary safety endpoint or analyses, and that these would be discussed with the FDA at the pre-NDA meeting). Thus, the entire analytical framework was developed with the FDA "post-hoc."[15] But even if the statistical analyses used by FibroGen deviated from a method purportedly agreed upon with the FDA (they did not), the CAC still does not plead fraud. In *In re MELA Sciences, Inc. Securities Litigation*, 2012 WL 4466604 (S.D.N.Y. Sept. 19, 2012), plaintiffs alleged that the company, which was developing a device to detect skin lesions, fraudulently reported "positive topline results" from a clinical trial. Although the company said the trial was conducted in a manner consistent with a protocol agreement with the FDA, it later disclosed a letter from the FDA stating that the device was not approvable because the clinical trial had departed from the protocol agreement. Plaintiffs

[15] Nor was it misleading for the Company to only share its interpretation of the data based on the primary safety analyses submitted in the NDA (*see supra* at 8). The securities laws "do not create an affirmative duty to disclose any and all material information. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). "[A] company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *In re Rigel Pharms., Inc. Sec. Litig.*, , 697 F.3d 869, 880 n.8 (9th Cir. 2012).

sued, alleging that defendants failed to disclose that the trial deviated from the agreed-upon protocol in that it, among other things, "ultiliz[ed] an unsound statistical analysis" and falsely reported the accuracy rate. *Id.* at *2. The court found plaintiffs could not state a claim, holding, "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial. [The complaint] alleges no facts demonstrating that defendants' publicly expressed opinions were different than or contradicted by the true opinions of the individual defendants." *Id*. at *13. Moreover, as the Second Circuit explained in another case, statements relating to clinical trial results are not misleading even if others "disagreed with Defendants' interpretation of the data."[16] *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016); *see also DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) ("[a]lthough Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim").

5. Statements of Optimism or Opinion

Plaintiffs' challenges to other statements fail because they are corporate optimism, on which "investors do not rely." *Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *11 (N.D. Cal. Sept. 27, 2012). This includes statements that:

- the data, roxadustat's profile, and interaction with the FDA were "positive" (#56, 57, 88-89), "good" (##11, 26, 57-58, 72, 85-86, 89), "favorable" or "trending favorably" (##14, 68, 87), "right" (#63), and the NDA submission was "complete[]" (#73, 75);
- the data was "encouraging" (##7, 12), "extremely clean" (#40), "excellent" (##49, 60, 65, 69), "robust" (##7, 44, 71), "reassuring" (#62); or "strong" (##67, 73-74, 92);
- the Company found the safety data "compelling" (##23, 39, 50-51, 53-54, 66, 71), and felt "comfortable" (##18, 21, 34), "confident" (##27, 28, 72-73, 76-77, 80, 82, 91, 93), "excited" (##10, 13, 24, 42), "pleased" (#26) or "good" (##61, 86) about it.

Statements that results were "very positive" or the company had a "strong" product "constitute run-of-the-mill corporate optimism on which no reasonable investor would rely." *In re Copper*

[16] Statements expressing confidence or excitement about roxadustat's safety data include Neff's statement that the "positive safety data give us confidence as we progress in preparation for the U.S. NDA" (#11) and Conterno's statement that he was "very excited and delighted with the results that we got – out of cardiovascular safety" (#42). (*See also* ##10, 14, 18, 21, 26-27, 39-41, 47, 50, 58, 60-61, 68, 72, 73, 76, 77, 80, 86, 91, 93.) These statements are inactionable as the CAC fails to allege these were not honestly-held, and they are statements of corporate optimism. *See infra at* Section IV.A.5.

Mountain Sec. Litig., 311 F. Supp. 2d 857, 869 (N.D. Cal. 2004); *Jasin v. VIVUS, Inc.*, 721 F. App'x 665, 667-68 (9th Cir. 2018) (approval "looking good" was "'mildly optimistic, subjective assessment[s]'" insufficient to plead fraud). The same is true for statements that a product had an "excellent" or "compelling" risk/benefit profile. *Kovtun*, 2012 WL 4477647, at *11.

These are also opinions as they "inherently reflect the speaker's assessment of and judgment about the underlying circumstances." *Markette v. XOMA Corp.*, 2017 WL 4310759, at *4 (N.D. Cal. 2017); *see In re LifeLock, Inc. Sec. Litig.*, 690 F. App'x 947, 951 (9th Cir. 2017) (what defendants "believe[d]" or "fe[lt]" are classically "opinion"). Plaintiffs fail to allege the opinions were not genuine, thus the statements are not actionable. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1021-22 (9th Cir. 2005).

6. Forward-Looking Statements

Many of the challenged statements, or portions thereof, are forward-looking and therefore not actionable under the PSLRA's safe harbor. These include statements about (1) the potential approval of the NDA (##5, 11, 21, 34, 60, 82, 89, 93), (2) what label the FDA might require for roxadustat if approved (##21, 42, 49, 51, 55, 67), and (3) roxadustat's potential (##1, 6, 14, 24, 44, 56, 63, 93, 86). *Kovtun*, 2012 WL 4477647, at *12; *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 403-04 (S.D.N.Y. 2018) (that treatment "could be clinically beneficial" or "potentially" treat illnesses are "clearly protected as forward-looking statements"). Many of the forward-looking statements were identified as such and accompanied by meaningful cautionary language. *Intuitive Surgical*, 759 F.3d at 1058. Those statements, and others not identified as forward-looking, are also protected under the second prong of the safe harbor, as Plaintiffs fail to allege that any Defendant had "actual knowledge" any statement was false or misleading when made – a standard even more stringent that scienter (which, as discussed below, Plaintiffs also fail to satisfy). *Id.*; 15 U.S.C. § 78u-5(c)(1)(B); *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1070 n.5 (N.D. Cal. 2001). Defendants' Appendix indicates which safe-harbor prong applies to each statement, where it is identified as forward-looking, and where cautionary language is found.

B. Plaintiffs Fail to Adequately Plead Scienter

The CAC should be dismissed on the independent ground that it fails to adequately plead scienter with regard to any Defendant. While heavy on rhetoric and accusation, the CAC lacks particularized "facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 974 (9th Cir. 1999). For alleged omissions, Plaintiffs must allege "a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco*, 552 F.3d at 991. Scienter must be pled "with respect to each of the individual defendants." *Or. Pub. Emps. Ret. Fund*, 774 F.3d at 607. Allegations must be "[p]ersuasive, effective, and cogent," giving rise to an inference of scienter that is "at least as compelling as any opposing inference," a standard "not easy to satisfy." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323-24 (2007); *Webb v. Solarcity Corp.*, 884 F.3d 844, 855 (9th Cir. 2018). The CAC falls well short of meeting these exacting standards with regard to any Defendant. Indeed, the far more compelling inference is that FibroGen and the Individual Defendants acted in good faith throughout the Class Period.

1. The Most Compelling Inference Is Good Faith

In addition to reviewing Plaintiffs' scienter allegations individually, the Court must view them holistically to determine whether the CAC meets the PSLRA's heightened pleading standards. When that is done, the far more compelling inference to be drawn is one of good faith.

The holistic review calls for a "practical and common-sense perspective." *S. Ferry LP v. Killinger*, 542 F.3d 776, 784 (N.D. Cal. 2008). Yet Plaintiffs' theory has already been rejected as nonsensical by the Ninth Circuit. In *Nguyen v. Endologix, Inc.*, plaintiffs alleged that defendants misled the market about the likelihood and timeline of FDA approval by failing to publicly disclose "unacceptable safety risks" that purportedly doomed the drug's prospects of approval. 962 F.3d 405, 415 (9th Cir. 2020). The Ninth Circuit rejected the theory noting that it "encounter[ed] an immediate first-level problem: why would defendants promise the market that the FDA would approve [the product] if defendants knew the FDA would eventually figure out

that [the product] could not be approved." *Id*. Plaintiffs' theory depended on "the supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout," which made little sense. *Id*. Because the theory was not "plausible," the Ninth Circuit found that plaintiffs failed to plead scienter and affirmed dismissal. *Id*. *See also Patel v. Seattle Genetics, Inc.*, 2018 WL 2359137, at *9 (W.D. Wash. May 24, 2018) (no scienter where defendants "cooperat[ed] with the FDA" and "expended significant time and money to develop" drug while adverse events would "inevitably" be discovered and drug would "be shut down").

Plaintiffs' theory of scienter in this case is equally unavailing. Indeed, it has the same first-level problem the Ninth Circuit found in *Nguyen*: it makes no sense. Just as in that case, Plaintiffs would have the Court believe that FibroGen and the Individual Defendants conspired to artificially inflate the Company's stock price though they knew the truth would eventually come out during the FDA's review of the roxadustat NDA and they would face the inevitable fall out. The theory here is even more preposterous in that it requires FibroGen to have colluded with its development partner, the much larger and independent AstraZeneca, as it too disclosed the same allegedly false and misleading information. (*See* Ex. Q.) If that were not enough to raise deep skepticism, the theory also requires one to believe that the fraud was carried out by a group of six individuals with significantly different tenures at the Company. Conterno and Eisner both joined FibroGen after Neff's death and, in Eisner's case, after Yu's retirement was announced. There are no allegations of relationships between any of them. Schoeneck served just four months as interim CEO, yet he was in the midst of the fraud, according to Plaintiffs. And Cotroneo, the Company's CFO, is not alleged to have had any involvement in the clinical trials, the analysis of the data from those trials, or interactions with the FDA. It just does not make sense.

It is also important to note that the CAC does not allege any direct interaction between the confidential witnesses ("CWs") and *any* Defendant. *See infra* at 27-28. Not a single conversation, document, or meeting is alleged supporting the inference that any defendant was aware of a risk of misleading investors – let alone, that a defendant chose to intentionally or recklessly ignore that risk. *Rigel Pharmaceuticals*, 697 F.3d at 883, is instructive. There plaintiff challenged the company's disclosure of efficacy and safety results, claiming that it misled

investors by disclosing results of a clinical trial without also disclosing that a "country effect" showed better efficacy results by patients in Mexico compared to the United States, and by failing to report all incidents of hypertension. *Id*. The Ninth Circuit affirmed the dismissal of plaintiff's claim. It held that, *even* if plaintiff had "adequately pled that all of the defendants had knowledge of the detailed clinical results at the time the allegedly false statements were made," plaintiff had failed to plead that "defendants believed" they made false statements. *Id*. It was not enough to allege that defendants may have been aware of a "country effect" or knew they were not sharing all hypertension data, plaintiff also needed to allege that defendants knew (or were reckless in not knowing) that the failure to disclose such information rendered their statements misleading. *Id*. at 883-84. No such facts are alleged here.

Furthermore, Defendants' optimistic statements regarding roxadustat's safety profile and possible FDA approval must be viewed in the light of the tremendous success the drug was having before other regulators around the world as a treatment for CKD anemia in DD and NDD patients. Indeed, in December 2018 and August 2019, roxadustat received regulatory approval in China – the second largest pharmaceutical market (by country) in the world.[17] (Ex. W at 3.) Only a month later, in September 2019, Japan – the world's third largest market – also approved the drug. (*Id*.) And on August 19, 2021, just days after the FDA issued its complete response letter, the European Commission approved Roxadustat, covering four of the next five biggest markets. (Ex. ZZ.) That is, within days of the end of the Class Period, roxadustat was approved for sale in eight of the ten largest pharmaceutical markets in the world. It is little wonder that Defendants felt good about roxadustat's safety profile and prospects in the U.S.

Moreover, far from an admission of guilt, the Company's voluntary April 6, 2021 press release undermines any inference of scienter. The results of the additional analyses included in that release, all of which had already been shared with the FDA, did not result in the withdrawal of the analyses disclosed in 2019 or indicate any issue with the integrity of the underlying data. (Ex. PP.) In fact, the 2021 release repeated the earlier analyses and added more information

[17] https://www.statista.com/statistics/245473/market-share-of-the-leading-10-global-pharmaceutical-markets/

based on additional analyses. (*Id.*) A "subsequent release of more extensive information" does not render the previously shared information false or misleading "even if some investors might have wanted more extensive information" earlier. *Rigel Pharms.*, 697 F.3d at 880 n.9. Moreover, the decision to disclose the additional analyses in April 2021 is not an act consistent with an intent to mislead; it is just the opposite. And the fact that a new CEO (Conterno) and a new CMO (Eisner), upon digging into the analyses and underlying data, concluded that additional disclosures should be made should come as no surprise. Given that there is no requirement under the securities laws to disclose all material information (*Matrixx*, 563 U.S. at 44), the decision as to what information to disclose related to complex clinical trial results, the analysis of those results, and the interactions with the FDA related to those results, is a difficult and complex one facing every publicly-traded life sciences company.

2. Plaintiffs Fail to Adequately Allege Scienter As To Any Defendant

Stock Sales. Plaintiffs rely heavily on stock sales during the 31-month Class Period (¶¶ 253-55) to support their effort to plead scienter. That reliance is badly misplaced. Defendants' trading activities negate any inference of scienter and provide strong support to infer the opposite.

Insider stock sales may provide circumstantial evidence of scienter only when they are "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed information," that is, the ongoing fraud. *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1066-67 (9th Cir. 2008) (quoting *In re Silicon Graphics Inc. Sec. Litig.,* 183 F.3d 970, 986 (9th Cir. 1999). This well-established rule makes sense as, absent such suspicious activity, an individual may well have been "simply trading in line with prior patterns, and selling without regarding to the timing and substance" of public statements or adverse information. *Id.* If a defendant "sold nothing at all" during the class period, it "suggest[s] that there was no insider information from which to benefit." *Id.* And if "defendants collectively sold a [] greater number of shares during an equal period of time just ***before*** the class period than they did ***during*** the class period," this ***rebuts*** an "inference of bad faith." *In re Apple Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989).

A comparison of the trading activity in the 31 months before the Class Period and the 31

months during the Class Period negates any inference of scienter ((Kasner Decl. ¶ 61):

Individual	Pre-Class Period Sales *(31 months)**	Class Period Sales *(31 months)***	Difference
Neff	2,399,656	683,448	-1,716,208
Yu	219,187	39,456	-179,731
Cotroneo	335,434	149,226	-186,208
Schoeneck	12,000	10,000	-2,000
Conterno	N/A	0	N/A
Eisner	N/A	0	N/A
TOTAL	**2,966,277**	**882,130**	**-2,084,147**

**(Shares Sold Between May 20, 2016 - December 20, 2018) **(Shares Sold Between December 20, 2018 - July 15, 2021)*

As set forth above, the Individual Defendants, along with Neff, collectively sold nearly 3 million shares of FibroGen stock in the 31 months before the Class Period (before any inflation caused by the alleged fraud) compared to fewer than 900,000 shares during the 31-month Class Period (when the price was allegedly artificially inflated). While Plaintiffs would have the Court conclude that the Individual Defendants were the worst fraudsters in the world as they failed to take advantage of their misdeeds, the far more compelling – and only cogent – conclusion to reach from these facts is that they simply were not acting with an intent to deceive anyone.

Plaintiffs' theory finds no additional support when sales are analyzed by individual. Neff, Yu, Cotroneo and Schoeneck all sold substantially more shares in the period before the Class Period than during. To be fair, both Neff and Yu were not employed by FibroGen the entire time: Neff passed away in August 2019, eight months into the Class Period, and Yu left the Company on December 20, 2020, 24 months into the Class Period. But, comparing their Class Period sales to the eight- and 24-month periods before, respectively, still does not support scienter: Neff sold 584,904 shares pre-Class Period compared to 638,448 during, and Yu sold 212,154 shares pre-Class Period compared to 39,456 during. (Kasner Decl. ¶¶ 67-68.) As for Conterno and Eisner, they each joined FibroGen during the Class Period and sold no shares. Conterno actually purchased shares in June 2020, while allegedly "artificially inflated." (Kasner Decl. ¶ 70); *See In re Leapfrog Enter., Inc. Sec. Litig.*, 237 F. Supp. 3d 943, 952 (N.D. Cal. 2017) (explaining that

purchase of stock "strongly weighing against scienter").

Finally, the CAC fails to acknowledge that each and every stock sale alleged during the Class Period was made pursuant to 10b5-1 plans. (Kasner Decl. ¶ 69.) Such non-discretionary sales negate an inference of scienter and support an inference of good faith. *See City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1069 (N.D. Cal. 2012).

Group Pleading. Although required to plead scienter separately as to each defendant and with regard to each statement alleged to have been made by him or her, the CAC largely groups all individuals together claiming that "Defendants," collectively, acted with scienter. *See e.g.,* (¶ 242) (alleging scienter based on "***Defendants'*** withholding of Roxadustat safety results from the FDA prespecified analysis"). But such "generalized 'everyone did everything' allegations" are "simply insufficient." *Cheung v. Keyuan Petrochemicals, Inc.,* 2012 WL 5834894, at *4 (C.D. Cal. Nov. 1, 2012). Further, the group allegations make no sense. For example, the CAC points to what it calls "***Defendants'*** specific admission that they had manipulated the crucial clinical trial results" on April 6, 2021. (¶ 237.) But Yu retired from FibroGen almost four months earlier and made no statements that day. (*See* ¶ 23.) Neither Schoeneck nor Cotroneo are alleged to have spoken on that date either, and Neff died years earlier. (¶¶ 222-29.) The CAC also relies upon ***"Defendants'*** ... confirm[ation of] their personal participation in the pre-NDA meeting with the FDA" in July 2019. (¶ 245.) But Neff could not have "confirmed" his participation as he was dead, and Conterno and Eisner had not yet even joined FibroGen at the time of the pre-NDA.

The other typical scienter theories in the CAC also fail to give rise to any inference of scienter. The CAC alleges that "Defendants" stood to "receive tens of millions of dollars in compensation," including bonuses "directly tied" to regulatory and commercial milestones (¶¶ 138, 254) and that FibroGen stood to receive "highly lucrative milestone payments" from AstraZeneca (¶ 256). But, as the Ninth Circuit has long made clear, "routine business objectives, without more, cannot normally be alleged to be motivations for fraud" as "to hold otherwise would be to support a finding of fraudulent intent for all companies." *Lipton v. Pathogenesis*, 284 F.3d 1027, 1038 (9th Cir. 2002). "[I]ncentives to obtain 'milestone' payments" do not contribute

to an inference of scienter. *Constr. Laborers Pension Tr. of Greater St. Louis v. Neurocrine Biosciences, Inc.*, 2008 WL 2053733, at *7–8 (S.D. Cal. May 13, 2008). Nor are compensation and "executive-level bonuses" indicative of scienter, especially where the operative complaint (like the CAC) fails to "includ[e] comparisons to previous years' bonuses." *In re Downey Secs. Litig.*, 2009 WL 2767670, at *13 (C.D. Cal. Aug. 21, 2009) (bonus criteria not indicative of scienter where it "was only one of three factors considered in determining executive bonuses").

The CAC also points to various newspaper articles and analyst reports in an apparent effort to support its scienter allegations. (*See e.g.,* ¶¶ 238-43.) Not surprisingly, though fatal to the effort, the CAC fails to allege that any of these third-parties had interactions with any Defendant or otherwise had knowledge of their state of mind with regard to any act or statement. As a result, their statements are pure speculation and conjecture, no more credible under the PSLRA than conjecture or speculation directly from Plaintiffs. *In re Wet Seal, Inc. Sec. Litig.*, 518 F. Supp. 2d 1148, 1172-73 (C.D. Cal. 2007) ("[c]onclusory allegations of wrongdoing are no more sufficient if they come from a newspaper article than from plaintiff's counsel"); *see also Campo v. Sears Holding Corp.*, 371 F. App'x 212, 215 (2d Cir. 2010) ("press speculation about defendants' motives" are not "specific, well-pleaded facts").[18]

CW Allegations. The allegations attributed to three former AstraZeneca employees also fail to give rise to an inference of scienter. As the Ninth Circuit has made clear, allegations attributed to "confidential witness statements may only be relied upon where the confidential witnesses are described 'with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Zucco*, 552 F.3d at 995. The Court must "look to 'the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and

[18] Plaintiffs also rely on a core operations inference, which may be used in 'exceedingly rare" circumstances to impute "knowledge of 'facts critical to a business's core operations.'" *S. Ferry*, 542 F.3d at 783, 785. But applying the inference simply because, as Plaintiffs contend, the alleged fraud related to "FibroGen's single most important drug" (¶ 246) would "eviscerate the core-operations test and turn it into an automatic presumption of comprehensive knowledge on the part of management." *Browning v. Amyris, Inc.*, 2014 WL 1285175, at *15 (N.D. Cal. Mar. 24, 2014); *see also In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1064 (9th Cir. 2014) (core operations inference does not apply where alleged omission involved "flagship product").

plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* The CAC comes nowhere close to meeting this standard, and it contains *no* corroborating allegations from other sources. First, all CWs are alleged to have had sales or commercial roles at AstraZeneca. (*See* ¶¶ 121 n.8; 122 n.9; 123 n.10.) The CAC does not allege that any CW was involved in roxadustat clinical trials, analysis of clinical data, submission of the NDA, or communications with the FDA. And the CAC does not allege any CW had direct interaction with *any* Defendant. Thus, the CW allegations do not establish "personal knowledge of the defendants' mental state." *Ferraro Family Found., Inc. v. Corcept Therapeutics Inc.*, 501 F. Supp. 3d 735, 766 (N.D. Cal. 2020) (rejecting allegations of ten CWs that said nothing about "personal knowledge of the [defendants] state of mind or that they communicated with [defendants]"). Second, the statements attributed to them are not indicative of scienter. According to the CAC, the CWs stated that unnamed FibroGen executives were "shady," FibroGen drove the NDA process, and similar generalized statements. But these lack specificity as to what actions were taken by the FibroGen executives, when they took such actions, or even who took such actions. They are not indicative of scienter.

3. Plaintiffs Fail to Allege Scienter as to Each Individual Defendant

Remarkably, the CAC is essentially *silent* as to the state of mind of any Individual Defendant. Indeed, Plaintiffs fail to allege "a single fact showing what each defendant knew, when he/she knew it, or how he/she acquired that knowledge." *In re Verisign, Inc., Derivative Litig.*, 531 F. Supp. 2d 1173, 1207 (N.D. Cal. 2007). As a result, the CAC fails to raise a strong and compelling inference that any Individual Defendant acted with fraudulent intent.

Enrique Conterno (Chief Executive Officer beginning January 2020). Aside from compensation, the CAC's scienter section mentions Conterno *once*, quoting his statement that the NDA "described both sets of analyses including the statistical methodologies and the stratification factors used." (¶ 245.) It is unclear how this undeniably true statement suggests that Conterno acted with fraudulent intent each time he discussed the safety study between February 25, 2020 and June 20, 2021. Conterno was not even at FibroGen when the safety study was designed, when the statistical analyses were done, or when the Company first disclosed safety

results in 2019. There are zero allegations about what Conterno knew, or when. And the fact that he sold no stock and *bought* shares during the Class Period undermines an inference of intent.

Pat Cotroneo (Chief Financial Officer). Cotroneo is named as a defendant only because he signed the Company's 10Q and 10K filings with the SEC, which include allegedly false and misleading statements about the roxadustat clinical trials. But other than identifying Cotroneo as a defendant, providing information about stock sales and compensation, and noting that he signed the SEC filings, the CAC is *entirely silent* on his knowledge or involvement in clinical and regulatory activities, much less the roxadustat safety studies. In fact, while Cotroneo is identified in Plaintiffs' Appendix as a "speaker" of six statements (##22, 28, 37, 38, 45, 58), they identify only *one* fact (stock sales) to support scienter as to only *one* statement (#22). And, as stated above, Cotroneo's stock sales negate any inference of scienter.

Dr. Mark Eisner (Chief Medical Officer beginning December 21, 2020). Eisner did not join FibroGen until December 2020 – 24 months into the Class Period, a full year after the NDA filing, and long after any decision was made about which stratification factors to use or what results to share publicly. (¶ 26.) Indeed, Eisner is alleged to have made statements on only two dates near the end of the Class Period: on March 1, 2021 (expressing his "confidence in the completeness of the NDA submission, [and] the strength of our data"), and on April 6, 2021 (opining that, even with the pre-specified stratification factors, roxadustat's safety profile remains positive and is comparable to the comparators). The CAC fails to allege that these were not his honest opinions at the time he made the statements. *Sanofi-Aventis*, 774 F. Supp. 2d at 567. Plaintiffs' Appendix identifies only two "facts" that purportedly establish scienter: his role "overseeing all global clinical development and regulatory affairs for FibroGen" and his 2020 compensation. Nothing more. That falls well short of the PSLRA's heightened pleading standards; it says nothing about Dr. Eisner's state of mind at any time. *See Verisign*, 531 F. Supp. 2d at 1207 (plaintiff must allege particularized facts "showing what each defendant knew, when he/she knew it, or how he/she acquired that knowledge"). It belies common sense to infer that Eisner intended to mislead investors by making the purported corrective disclosure that Plaintiffs allege revealed the fraud. (*See* ¶ 265.)

Thomas Neff (CEO from December 2018 to August 2019). Neff passed away shortly after the Company's pre-NDA meeting with the FDA and *before* the Company disclosed its detailed pooled safety data in November 2019. Other than the misleading portrayal of his stock sales which, as discussed above, are insufficient to plead scienter, the CAC offers only one CW's speculation that he "had to have been all over this information" because "FibroGen 'was Tom [Neff's] company.'" (¶ 250.) But these are not well-pled allegation about Neff's state of mind. *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, 2019 WL 6877195, at *19 (N.D. Cal. Dec. 17, 2019) ("merely speculative awareness of Individual Defendants' knowledge is not enough"). There are zero particularized allegations about Neff's involvement or awareness, as such, the CAC fails to plead Neff's scienter.

James Schoeneck (Interim CEO from August 2019 to January 2020). The CAC alleges only two statements by Schoeneck in November 2019 during his short tenure as interim CEO, reiterating the topline results of the safety study. (##33, 37.) Plaintiffs do not allege that Schoeneck was involved in, or aware of, the decision behind which stratification factors to use, or which analyses to disclose. Nor was he an executive at the time of the purported "admission" on April 6, 2021. Without such particularized facts, the CAC does not plead scienter as to him. Schoeneck's compensation and stock sales are not sufficient either. *See supra* at IV.B.2.

Dr. Peony Yu (Chief Medical Officer until December 20, 2020). As set forth in Yu's Motion to Dismiss and Joinder filed concurrently, the CAC does not plead particularized facts that give rise to an inference that she acted with intent or recklessness when she made the statements attributed to her between December 20, 2018 and May 7, 2020. The CAC alleges no fact that suggests Yu did not believe that the results of the safety analyses were anything other than a reasonable interpretation of the data, or that her opinions were not honestly-held beliefs.

V. CONCLUSION

For the foregoing reasons, Defendants respectfully requests that the Court grant their Motion to Dismiss the CAC in its entirety, with prejudice.[19]

[19] Because the CAC does not state a primary violation, Plaintiffs' "control person" claim under Section 20(a) fails. *Rigel Pharms.*, 697 F.3d at 886.

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